CERTIFICATES OF CONFIDENTIALITY FOR PROTOCOL DEVELOPMENT

1.0 BACKGROUND

1.1 Purpose

Certificates of Confidentiality allow researchers to avoid the involuntary release of any portion of research records containing information that could be used to identify study participants. A certificate of Confidentiality protects the investigator and anyone else who has access to research records from being compelled to disclose identifying information in any civil, criminal, administrative, legislative or other proceedings whether federal, state, or local. Identifying information is broadly defined as any item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information that might identify a research subject.

Certificates can be used to promote participation in studies by assuring anonymity to participants. Certificates will be issued only when the research is of a sensitive nature, where protection is judged necessary to achieve the research objectives. For instance, a Certificate of Confidentiality may be granted if disclosure could have adverse legal consequences or damage financial standing, employability, insurability, or reputation of the participant. The Certificate will help researchers avoid involuntary disclosure which could expose subjects and their families to adverse economic, psychological, and social consequences.

1.2 History

Certificates of Confidentiality were originally authorized by a 1970 amendment to the Public Health Service Act, to protect participants in research on the use and effects of drugs. The authority to award Certificates was vested with the Secretary of the Department of Health and Human Services (DHHS). The authority was extended to research on “mental health, including research on the use and effect of alcohol and other psychoactive drugs” in 1977. In 1988, the statute was broadened so that Certificates could be sought to protect individuals participating in biomedical, behavioral, clinical and other research, and the authority to issue Certificates was delegated to the Office of the Assistant Secretary for Health (OASH). Authority to issue Certificates for drug, alcohol, and mental health research was delegated to National Institute of Mental Health (NIMH). With the reorganization of the OASH in 1996, its Certificate authority was decentralized to the NIH institutes, and the NIH Director further delegated this authority to certain NIH officials

(Institute and Center [IC] Directors, Deputy IC directors, and Executive Officers). Each IC had the option of issuing its own Certificates, but also had the option instead to continue to use NIMH because of its experience and expertise as a Service Center. The NCI chose to accept authority to issue Certificates of Confidentiality for extramural research projects funded by NCI and intramural research projects with NCI PIs. NIMH continues to serve as the NIH Service Center for issuing Certificates for eligible cancer research-related projects not supported or sponsored by NCI.

1.3 Types of Projects Covered

NCI issues Certificates sparingly for single, well-defined projects rather than for groups or classes of projects. An exception is cooperative multisite projects, in which a coordinating center or "lead" institution designated by the government Program Director can apply on behalf of all member institutions, and a single Certificate providing protection to all participating sites is issued. In this case, the application must list each participating unit, its address, and the Project Director of the participating unit on the first page of the application. The lead institution is responsible for distributing copies of the Certificate to each center of site.

1.4 Extent and Limitations of Coverage

Certificates of Confidentiality can be used to cover biomedical, behavioral, clinical, or other research, whether or not it is federally funded. However, NCI will issue Certificates only for eligible cancer-related research projects which are supported by NCI. Researchers should take appropriate steps to safeguard research results so individuals having access to medical records (including those who may access the records with the subject's consent) cannot access the research results or learn the identity of research participants.

Certificates protect against involuntary disclosure; however, information may be voluntarily released under certain circumstances. For example, research subjects may disclose or consent to the disclosure of information (including research information) in their medical records to an insurer, and researchers may not use the Certificate to refuse disclosure under this circumstance. In addition, researchers are expected to make arrangements with local and state authorities to satisfy communicable disease reporting requirements, and subjects should be informed of this possibility in the informed consent document. Moreover, Certificates do not authorize researchers to refuse to disclose information about subjects if authorized DHHS personnel request such information for an audit or program evaluation or if such information is required by the Federal Food, Drug and Cosmetics Act.

1.5 Period of Coverage

Certificates are issued for the specific time period set forth in the Certificate. Certificates are effective on the date of issuance or upon the commencement of the research project, if that date is later than the date of issuance. An extension of coverage of an active Certificate must be requested if the research extends beyond the expiration date of the original Certificate. However, data collected while a Certificate is in effect remains protected after the Certificate expires and in perpetuity. Applicants are advised to elect a period of coverage that may overestimate, rather than underestimate, the time required to complete the project. Requests for extensions of Certificate coverage should be made three months prior to the expiration date. They should be accompanied by a justification, documentation of the most recent IRB approval, and the new expected completion date of the research project.

1.6 Eligibility Criteria

Certificates are issued sparingly and are only appropriate when the research information gathered is of a sensitive nature, and protection is deemed necessary to achieve the research objectives while protecting the study participants' confidentiality and privacy. Studies gathering information which, if disclosed, could reasonably lead to social stigmatization or job or medical/life insurance discrimination, would qualify for a Certificate. Projects eligible for Certificates must involve the collection of sensitive information that, if disclosed, could be damaging to an individual's financial standing, reputation, insurability, or employability. Examples of cancer research projects which would be eligible include, but are not limited to, the following:

1.6.1 Projects involving genetic testing for cancer predisposition. Studies involving the collection and storage of biological samples for use in subsequent research could be eligible if the scope and purposes of such research can be adequately specified.

1.6.2 Studies that collect information on an individual's psychological well-being or mental health, or that include psychiatric conditions as entry criteria or confounding variables.

1.6.3 Research which requires information on sexual attitudes, preferences, or practices.

1.6.4 Research on human immunodeficiency virus (HIV)/AIDS.

1.6.5 Studies of cancer risk related to substance abuse or research involving other illegal

risk behaviors (*e.g.,* purchase of tobacco products or alcohol by minors).

1.6.6 Research in which participants may be involved in class action litigation related to exposures under study (*e.g.,* breast implants, medications, environmental or occupational exposures).

In other circumstances, personally identifiable information may be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation. The above eligibility criteria apply to NCI-funded research; research in other fields may involve other kinds of personally sensitive information needing Certificate protection.

1.7 Ineligible Applications

Projects which are not research-based or research-related are ineligible for a Certificate of Confidentiality, as are projects which have not received IRB review and final approval. Projects collecting information which, if disclosed, is not deemed to involve significant harm or damage to the subject are not eligible.

2.0 PROCEDURES FOR APPLYING

2.1 NCI Intramural Investigators

When possible, application for a Certificate should be made in conjunction with initial or annual IRB review of research proposals. PIs should complete a brief application form (Attachment E-1) which will be appended to the research protocol for submission to the IRB. Protocols submitted to the Clinical IRB and the Special Studies IRB will be reviewed for human subject safety concerns. When they receive final approval, protocols will be forwarded to the Certificate Subcommittee as appropriate.

When applications for Certificates are out of synchrony with the IRB process, PIs may request Certificates by completing and submitting an application form (Attachment E-2) to the Certificate Coordinator (Section 2.5), along with the research protocol and documentation of the most recent IRB review and approval (memo signed by IRB Chair).

2.2 Extramural Investigators

Investigators should complete an application form (Attachment E-3) with the requisite IRB

review documentation and a copy of the informed consent/assent forms to be used in the study, as approved by the IRB. Applicants need not submit supplemental materials, such as the research protocol itself.

2.3 Review Procedures

Applications from NCI intramural investigators as well as from NCI-supported extramural investigators are reviewed and recommended for review by the Certificate Subcommittee of the NCI IRBs which meets on a monthly basis or as needed to review Certificate applications. Applications recommended for approval by the Certificate Subcommittee are forwarded to the NCI Deputy Director for final approval and signature; when this is obtained, applicants are informed by memo from the Certificate Subcommittee Chair.

2.4 Modifications to Projects and Changes in Participating Institution

Requests for modifications or amendments should be made three months prior to the needed date. These requests should be accompanied by a justification and documentation of the most recent IRB approval. An amendment to an existing Certificate should be requested when a PI relocates to a new institution. Requests for modifications and amendments will be reviewed by the Certificate Coordinator and, in consultation with a member of the Certificate Subcommittee, recommend for approval or disapproval. If a requested modification or amendment represents a substantial change in the research scope of a project, the Certificate Subcommittee may require that a new Certificate be sought.

2.5 Agency Contacts

To obtain or submit an application or to request an extension or amendment for an existing Certificate awarded by NCI, contact:

Ms. Lynn Sayers
Certificate Coordinator
NCI
6120 Executive Boulevard, Room 214
Rockville, Maryland 20852
TEL: 301-402-7221
FAX: 301-402-4279
E-mail: ls67i@nih.gov

For further information about Certificates of Confidentiality, contact:

Susan M. Sieber, PhD
Associate Director for Special Projects
NCI
9000 Rockville Pike
Building 31, Room 11A48
Bethesda, Maryland 20892
TEL: 301-496-5946
FAX: 301-496-2471
E-mail: siebers@pndce.nci.nih.gov

To obtain or submit an application or to request an extension or amendment for an existing Certificate awarded by a government agency other than NCI, contact:

Ms. Olga Boikess
NIMH
5600 Fishers Lane
Rockville, Maryland 20857
TEL: 301-443-3877

3.0 QUESTIONS AND ANSWERS ABOUT CERTIFICATES OF CONFIDENTIALITY

3.1 What are Certificates of Confidentiality?

A Certificate of Confidentiality protects the privacy of subjects in health research projects against compulsory legal demands (*e.g.*, court orders and subpoenas that seek the names or other identifying characteristics of research subjects) made of the investigator(s).

3.2 What is the purpose of the certificate?

The certificate was developed to protect against the involuntary release of personally identified research information of a sensitive nature sought through any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Certificates of Confidentiality were first issued by the U.S. Department of Health and Human Services (DHHS) as a means of enabling drug abuse-related research projects where, in the course of the research, the study participants may be providing legally incriminating or sensitive personal information [1]. The authority was granted under the Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513, Section 3(a). The protection afforded by Certificates of Confidentiality thus made

possible research in substance abuse that may not have been possible. In 1974, an amendment extended coverage of the Certificates to research on "mental health, including research on the use and effect of alcohol and other psychoactive drugs." In 1988, the law was amended yet again to broaden the use of Certificates to safeguard individuals participating in biomedical, behavioral, clinical, and other research [2]. The statute, as amended, pertains to a broad spectrum of cancer-related research projects.

3.3 What protection does a certificate afford?

Investigators can interpose a Certificate to avoid being required to release personally identifiable research information about individual study participants. Under this statute: "The Secretary [of the Department of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, and on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals" (Public Health Service Act 301 (d), 42 U.S.C. 241 (d), as amended by Public Law No. 100-607, Section 163 (November 4, 1988).

A certificate is generally issued to a research institution for a single project (not broad groups or classes of projects). However, for cooperative multisite projects, a coordinating center or "lead" institution can apply for, and receive, a Certificate on behalf of all member institutions. The Certificate covers the collection of sensitive research information for a defined time period; information obtained while the Certificate is in effect is protected in perpetuity.

3.4 What types of projects are eligible for a certificate?

A certificate may be appropriate when the research information is of a sensitive nature, as determined by the Certificate Subcommittee of NCI's IRB, and the protection of a Certificate is necessary to achieve the research objectives while assuring the study participants' confidentiality. Studies gathering information which, if disclosed, could reasonably be expected to lead to social stigmatization or job or medical/life insurance discrimination, would qualify for a Certificate. Projects eligible for Certificates must involve the collection of sensitive information which, if disclosed, could have adverse legal consequences or be damaging to an individual's financial standing, reputation, insurability,

or employability. Examples of cancer research projects which would be eligible include but are not limited to:

3.4.1 Projects involving genetic testing for cancer predisposition. In general, studies involving the collection and storage of biological samples for incompletely specified future uses, but which might include genetic studies, might be considered eligible.

3.4.2 Studies collecting information on an individual's psychological well-being or mental health, or which include psychiatric conditions as entry criteria or confounding variables.

3.4.3 Research which requires information on sexual attitudes, preferences, or practices.

3.4.4 Research on human immunodeficiency virus (HIV)/AIDS.

3.4.5 Studies of cancer risk related to substance abuse on research involving other illegal risk behaviors (*e.g.,* purchase of tobacco products or alcohol by minors).

3.4.6 Research in which participants may be involved in class action litigation related to exposures under study (*e.g.,* breast implants, medications, environmental or occupational exposures).

These eligibility criteria apply to NCI-funded research; research in other fields may involve other kinds of personally sensitive information needing Certificate protection.

3.5 What projects are NOT eligible for a certificate?

Projects NOT eligible for a Certificate are:

3.5.1 Projects that are not research-based or research-related.

3.5.2 Projects that are not IRB-approved.

3.5.3 Projects collecting information which, if disclosed, is not deemed to involve significant harm or damage to the subject.

3.6 In what situations may data protected by a Certificate be disclosed?

Data that are protected by a Certificate may be disclosed under the following circumstances:

3.6.1 Voluntary disclosure of information by study participants themselves to physicians or other third parties, or authorization by study participants of release of information to insurers, employers, or other third parties.

3.6.2 Voluntary reporting by the investigator of information, such as child abuse or threat of other potential violence by the study participant to the participant or others, provided such intention is specified in the informed consent document.

3.6.3 Voluntary compliance by the researcher with reporting requirements of other state laws such as knowledge of a communicable disease, provided such intention is specified in the informed consent document.

3.6.4 Release of information by investigators to DHHS as required for audits of research records or to the FDA as required under the federal Food, Drug, and Cosmetic Act (21U.S.C. § 301 *et seq*).

3.7 What is the researcher's responsibility to participants in a study for which a Certificate has been granted?

The investigator may not represent the issuance of a Certificate to potential participants as an endorsement of the research project by DHHS or use it in a coercive manner for recruitment of participants. The investigator must use the authority of the Certificate to resist compulsory disclosure of individually identifiable research data.

The study participants should be informed that a Certificate is in effect, and be given a fair and clear explanation of the protection it affords, including the limitations and exceptions. This information may be included in the informed consent document or provided to the research participant in an additional information page. Suggested wording:

We have received a Certificate of Confidentiality from the federal government, which will help us protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of this study. The researchers involved in this project cannot be forced to disclose your identity or any information about you collected in this study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, you or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if you or your guardian requests the release of information about you in writing, (through, for example, a written request to release medical records to an insurance company),

the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

Study participants may also be given a copy of the Certificate, although this is not necessary it would impede the research. Study participants should be notified that a Certificate has expired if they are recruited to the study after the expiration date of the Certificate and an extension of the Certificate's coverage has not been granted.

3.8 How are certificates of confidentiality issued?

Under the Public Health Service Act and its amendments, the Secretary of the DHHS has the authority to grant Certificates of Confidentiality. Prior to 1996, Certificates were issued by the Office of the Assistant Secretary for Health of DHSS under a delegation of authority from the Secretary. Recently, the authority to issue Certificates has been delegated to the individual Institutes of NIH, and the NCI has accepted this authority for NCI-funded research projects. Investigators whose research is funded by federal government entities other than NCI may apply to NIMH for a Certificate, as described below.

Based on an application from the PI of a specific research project, a Certificate is granted in the name of that investigator's institution for that project. When more than one institution is participating in a project, the PI at the lead institution is responsible for applying on behalf of all sites, and a single Certificate is issued in which all participating sites are listed. For projects in which an investigator conducts research information within the United States, a Certificate may be issued for the project to the investigator at his domestic institution.

If the research scope of a project covered by a Certificate should change substantially, the PI should request an amendment to the Certificate; however, the Certificate Subcommittee may require a new Certificate depending on the extent of the change in scope. An extension of coverage must be requested if the research extends beyond the expiration date of the original Certificate, as research information collected after the expiration of a Certificate is not protected from compelled release

3.9 What is the process for applying to NCI for a certificate?

Extramural Investigators: Projects are not eligible for a Certificate unless they have been reviewed and approved by an IRB. Investigators should complete an application form* which solicits information about the project and the investigator, and submit it, along with

IRB review documentation and a copy of the informed consent/assent forms to be used in the study, to the NCI Certificate Coordinator. Applications must be signed by the PI and the Institutional Official.

Intramural Investigators: It is recommended that applications for a Certificate be made in conjunction with initial or annual IRB review of research protocols. When this is the case, investigators should complete an application form* which is attached to the protocol when it is submitted for IRB review. When applications are out of synchrony with the IRB process, investigators must complete and submit an application form* to the Certificate Coordinator, along with the research protocol and documentation of the most recent IRB review and approval.

*To obtain application forms, to submit a completed application, or to request an extension or amendment to an existing Certificate, the PI should contact:

Ms. Lynn Sayers
Certificate Coordinator
National Cancer Institute
6120 Executive Boulevard, Room 214
Rockville, Maryland 20852
Telephone: 301-402-7221
Fax: 301-402-4279
E-mail: Is67i@nih.gov

For further information about NCI Certificates of Confidentiality, contact:

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Telephone: 301-496-5946
Fax: 301-496-2471
E-mail: siebers@epndce.nci.nih.gov

Non-NCI Funded Investigators: Investigators interested in Certificates for research projects that are not funded or conducted by NCI may contact:

Ms. Olga Boikess
National Institute of Mental Health
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: 301-443-3877

3.10 How are extensions or amendments to existing certificates obtained?

Requests for extensions of an expiration date for a Certificate or for other amendments should be made three months prior to the needed date. These requests should be accompanied by a justification, documentation of the most recent IRB approval, and in the case of an extension, the new expected completion date for the research project. They should be directed to the NCI Certificate Coordinator at the address above.

3.11 Has the legality of certificates been challenged?

There have been court challenges to the confidentiality protections afforded by a Certificate. In 1973, the Certificate's authority was upheld in the New York Court of Appeals. The U.S. Supreme Court declined to hear the case.

3.12 What should an investigator do if legal action is brought to release personally identifying information protected by a certificate?

A Certificate of Confidentiality is a legal defense against a subpoena or court order to be

used by the researcher to resist disclosure. The researcher should seek legal counsel from his or her institution. The Office of General Counsel for DHHS is willing to discuss the regulations with the researcher's attorney. Should your NCI-issued Certificate be subject to court challenge, please notify:

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9000 Rockville Pike
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Bethesda, Maryland 20892
Telephone: 301-496-5946
Fax: 301-496-2471
E-mail: siebers@epndce.nci.nih.gov

References

1. Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law No. 91-513, 3(a).
2. Controlled Substance Act §502(c), 21 U.S.C. §872; Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Amendments of 1974, Public Law No. 93-282, §122; Health Omnibus Programs Extension of 1988, Public Law No. 100-607, §163.